

# Exhibit B

Confidential - Subject to Further Confidentiality Review

Page 1

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF ILLINOIS

3       B.P., A MINOR, BY DAWN                   )  
4       FRAGNOLI INDIVIDUALLY AS               )  
5       PARENT AND NEXT FRIEND                ) Case No.  
6    ) 13-cv-324-SCW  
7    )  
8    )

9       J.B., A MINOR, BY LINDA                ) Case No.  
10       LEJEUNE INDIVIDUALLY AS               ) 13-cv-326-SCW  
11       LEGAL CUSTODIAN AND NEXT               )  
12       FRIEND,                                    )  
13    )  
14    )

15                   VS.                            )  
16    )  
17    )

18       ABBOTT LABORATORIES, INC.,             )  
19    )  
20    )  
21       -----                                    )  
22    )  
23       AND OTHER RELATED ACTIONS             )  
24    )  
25       -----                                    )

26                   -C O N F I D E N T I A L -

27                   SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

28                   VIDEOTAPED DEPOSITION OF JAMES STECK, taken  
29       pursuant to Federal Rules of Civil Procedure 26 and  
30       30, by and before Dutcheen O. Cameron, RPR and  
31       Notary Public in and for the Commonwealth of  
32       Pennsylvania, at the Hyatt Regency Hotel, Foerster  
33       Boardroom, 1111 Airport Boulevard, Pittsburgh,  
34       Pennsylvania, on Friday, February 14, 2014, at 8:41  
35       a.m.

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<p style="text-align: right;">Page 354</p> <p>1 earlier Exhibit 433, which is the PDR continuing  2 the label for Depakene. Do you have that in front  3 of you? Is that Depakene or Depakote? Depakene.  4 A. Looking for it. There it is.  5 Q. All right. And in regard to the  6 statement that anti-epileptic drugs should not be  7 discontinued in patients in whom the drug is  8 administered to prevent major seizures because of  9 the strong possibility of precipitating status  10 epilepticus with a attendant hypoxia and threat to  11 life.  12 By this language did Abbott intend to  13 convey that Depakote should be used for  14 tonic-clonic seizures?  15 A. I don't believe that that was the  16 intention.  17 Q. Are you aware of any mechanism by  18 which absence seizures could cause hypoxia and  19 threat to life of a fetus?  20 A. Again, I'm not knowledgeable enough to  21 say whether it would or would not. I would just go  22 back to this statement that says it cannot be said  23 with any confidence that even minor seizures do not  24 pose some hazard to the developing embryo or fetus.</p>	<p style="text-align: right;">Page 356</p> <p>1 the FDA that it had no such approval?  2 MS. HARDWAY: Object to form.  3 A. Well, I guess for one thing, this is a  4 1985 label, and that letter -- the warning letter  5 was -- was it 1988?  6 BY MS. ABARAY:  7 Q. We have lots of labels if you want a  8 different year.  9 A. No, I get your point. Okay. But just  10 to go back to the question, I don't think that this  11 statement necessarily implies that Abbott was  12 suggesting that the product was approved for or  13 indicated for tonic-clonic seizures. I think this  14 is more or less a boilerplate statement. The one  15 thing I will say is that in addition to being  16 approved for tonic -- for absence seizures, the  17 approved indication said that Depakene was approved  18 as adjunctive therapy for multiple seizure types  19 that include absence. So possibly that statement  20 would be in there as a precaution to say, you know,  21 discontinuing drugs for patients who had seizures  22 that could lead to status epilepticus shouldn't be  23 abruptly -- or shouldn't be discontinued from their  24 treatment.</p>
<p style="text-align: right;">Page 355</p> <p>1 Q. All right. So a minor absence seizure  2 could cause a hazard to the fetus?  3 A. I guess what this statement is saying  4 is it's -- it wasn't known whether or not that's a  5 possibility.  6 Q. Okay. And so, sir, Abbott was aware  7 at the time that it was continuing to represent in  8 its label that even a small seizure could cause  9 damage to the fetus that any suggestion that the  10 product had been approved for tonic-clonic would be  11 in direct conflict with the letter that the firm  12 had received denying approval for that indication;  13 isn't that true?  14 MS. HARDWAY: Object to form --  15 A. Is your question --  16 MS. HARDWAY: -- outside the scope.  17 A. -- whether that statement would  18 suggest that Abbott felt that the product was  19 effective in tonic-clonic seizures?  20 BY MS. ABARAY:  21 Q. Yes. My question is was Abbott  22 continuing to imply in its product labeling that  23 the drug could be used for tonic-clonic when, in  24 fact, they had been specifically warned and told by</p>	<p style="text-align: right;">Page 357</p> <p>1 Q. So if the intention was to suggest  2 that Depakote or Depakene could be used for  3 tonic-clonic, that would have been incorrect?  4 MS. HARDWAY: Object to form.  5 A. Yes, I don't know -- I don't believe  6 that that was the intention, but yes, in answer to  7 your -- the question you asked.  8 BY MS. ABARAY:  9 Q. All right. Now, do -- do you have  10 like a 2000 label or I don't --  11 MS. HARDWAY: You had it.  12 MS. ABARAY: Did I grab it? I'm  13 sorry, they're getting away from me. Here we go.  14 * * *  15 (Whereupon, Deposition Exhibit No. 441 was  16 marked for identification.)  17 * * *  18 BY MS. ABARAY:  19 Q. Sir, I'm going to hand you the label  20 that we copied from the PDR in 2000. And we marked  21 this has Exhibit 441?  22 A. Okay.  23 Q. And I just picked this in general  24 because this is a label that has at the end what's</p>

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<p style="text-align: right;">Page 358</p> <p>1 now called the patient information leaflet?</p> <p>2 A. Yes.</p> <p>3 Q. And that would be the information that</p> <p>4 was drafted to provide consumers with information</p> <p>5 about teratogenicity so that the women taking the</p> <p>6 drug would have some communication about the risk;</p> <p>7 is that right?</p> <p>8 A. Yes. When you say consumers, I'm not</p> <p>9 sure what you mean. This was directed to patients</p> <p>10 who were using Depakote for treatment of migraine.</p> <p>11 Q. Right. And this was the information</p> <p>12 that Abbott was having distributed through doctors</p> <p>13 rather than having it prepared as a patient package</p> <p>14 insert for patients?</p> <p>15 A. Yes.</p> <p>16 Q. And so it's called at the top here</p> <p>17 patient information leaflet. In fact, what we</p> <p>18 have, it's a continuation of the product labeling,</p> <p>19 for instance, that would be in the PDR.</p> <p>20 A. Yes, but there were separate leaflets</p> <p>21 that were provided to physicians for their use and</p> <p>22 in discussing the information with patients and the</p> <p>23 patient would be given that copy of that leaflet.</p> <p>24 Q. Did you ever see the leaflets?</p>	<p style="text-align: right;">Page 360</p> <p>1 MS. ABARAY: No, it doesn't. He</p> <p>2 either heard it or he didn't hear it.</p> <p>3 A. I didn't hear. And, you know, I --</p> <p>4 there would be no reason that I would hear,</p> <p>5 actually.</p> <p>6 BY MS. ABARAY:</p> <p>7 Q. Did you ever -- were you ever informed</p> <p>8 that the company had run out of leaflets and needed</p> <p>9 to print new leaflets?</p> <p>10 A. No.</p> <p>11 Q. Did you ever have a patient contact</p> <p>12 the company and say I got this information in this</p> <p>13 leaflet, I want to talk to you about it?</p> <p>14 A. I wouldn't have received that type of</p> <p>15 call, but I don't know whether that happened or</p> <p>16 not.</p> <p>17 Q. Did the company ever conduct any type</p> <p>18 of a survey to determine the effectiveness of the</p> <p>19 distribution of leaflets to physicians as a means</p> <p>20 of communicating risk to patients?</p> <p>21 MS. HARDWAY: Object to form.</p> <p>22 A. Not as far as I'm aware.</p> <p>23 BY MS. ABARAY:</p> <p>24 Q. And you never, as a director of</p>
<p style="text-align: right;">Page 359</p> <p>1 A. Yes, I did.</p> <p>2 Q. And what did they look like?</p> <p>3 A. Well, they were in pads and, you</p> <p>4 know, in -- in a font size that could be easily</p> <p>5 read and -- so a pad would contain a number of</p> <p>6 copies of the leaflet which the physician could</p> <p>7 tear off and give to a patient.</p> <p>8 Q. And by what means did Abbott</p> <p>9 distribute these leaflets to physicians?</p> <p>10 A. They were distributed through the</p> <p>11 sales force.</p> <p>12 Q. And did you as the director of</p> <p>13 regulatory ever determine how effective this</p> <p>14 distribution of leaflets was to the physicians?</p> <p>15 MS. HARDWAY: Object to form.</p> <p>16 A. I personally did not. I mean, that</p> <p>17 was, again, a responsibility of another department.</p> <p>18 They were made aware and they were given clear</p> <p>19 direction as to what our commitment to FDA was.</p> <p>20 BY MS. ABARAY:</p> <p>21 Q. Did you ever hear of a doctor calling</p> <p>22 to ask for more leaflets?</p> <p>23 MS. HARDWAY: Object to form, calls</p> <p>24 for speculation.</p>	<p style="text-align: right;">Page 361</p> <p>1 regulatory, suggested that such a survey be</p> <p>2 conducted?</p> <p>3 MS. HARDWAY: Object to form.</p> <p>4 A. No, I did not.</p> <p>5 BY MS. ABARAY:</p> <p>6 Q. Have you ever reviewed any published</p> <p>7 literature on the effectiveness of the warning</p> <p>8 label for teratogenicity in Depakote?</p> <p>9 MS. HARDWAY: Object to form.</p> <p>10 A. Published literature specifically</p> <p>11 about the effectiveness of the Depakote warning</p> <p>12 letter, no.</p> <p>13 BY MS. ABARAY:</p> <p>14 Q. For instance, is there any published</p> <p>15 literature that describes the knowledge base that</p> <p>16 physicians have about the teratogenicity of</p> <p>17 Depakote as reflected in the label?</p> <p>18 A. I don't know whether there is or is</p> <p>19 not.</p> <p>20 Q. Did you ever require that Abbott -- or</p> <p>21 strike that.</p> <p>22 Did you as the director of regulatory</p> <p>23 affairs ever take action to send a dear doctor</p> <p>24 letter to physicians to inform them about the</p>

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